K080266

Vericom Co. Ltd. *Healthy and beautiful teeth with Vericom*

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: September 1, 2007

1. Company making the submission:

	Submitter
Name	VERICOM Co., Ltd.
Address	#606, 5th Dongyoung Venturestel 199-32, Anyang 7-Dong, Manan-Gu Anyang-Si, Gyeonggi-Do, Republic of Korea 430-817
Phone	+82 31 441-2881
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Contact	Myung-Hwan Oh
Internet	mh-oh@hanmail.net

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2. Device :
   Proprietary Name – Well-Pex™
   Common Name – Root canal filling Materials
   Classification Name – Resin, Root Canal Filling

3. Predicate Device :
   Metapex, META BIOMED CO. LTD. K032603

4. Description :
   Well-Pex™ is a temporary root canal filling material after pulpectomy, or for apexogenesis or apexification. It is also used as a good medicament for the treatment of infected root canals. Containing Calcium Hydroxide and Iodoform, it shows excellent radiopacity and prevention of microbial contamination. It has high fluidity and excellent accessibility into the root canal. Well-Pex™ is a premixed paste as a non-setting material and is very stable without any solidification or separation. And it is packaged in a convenient syringe with disposable tips, a plastic holder and disposable tip cap.

5. Indication for use :

Well-Pex™ is a biocompatible temporary or permanent root canal sealer, for use to stimulate healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition. To be used as a medicament for the treatment of infected root canals and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexegenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.

6. Review :

Well-Pex™ has the similar technological characteristics as the predicate device; device design, appearance, main materials and indication for use.

Well-Pex™ has the similar physical properties as the predicate device; flow, film thickness, Radiopacity, slubility and disintegration.

Well-Pex™ has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Vericom Co., Ltd. concludes that Well-Pex™ is safe and effective and substantially equivalent to predicate devices as described herein.

8. Vericom Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

606,5th Dongyoung Venturestel, 199-32, Anyang 7-dong, Manan-gu, Anyang-si, Gyeonggi-do 430-817, Korea

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

Vericom Company Limited
C/O Mr. Morten S. Christensen
Responsible Third Party Official
Underwriters Laboratories, Incorporated
455 East Trimble Road
San Jose, California 95131-1230

Re: K080266
Trade/Device Name: Well-Pex™
Regulation Number: 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: January 22, 2008
Received: February 1, 2008

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

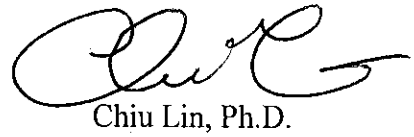
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 080266

Device Name: Well-Pex™

Indication for use:

Well-Pex™ is a biocompatible temporary or permanent root canal sealer, for use to stimulate healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition. To be used as a medicament for the treatment of infected root canals and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexegenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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